REMARKS

The Office Action dated December 26, 2008 and the Advisory Action of May 7, 2009 have been received and carefully noted. The above amendments and the following remarks are being submitted as a full and complete response thereto.

Claims 1-2, 4-6, 8-11, 13, 15, 17, 29-31, and 48-61 are pending in this application, with claims 1, 29, 48, and 59 being independent. By this Amendment, claims 1-2, 5, 10-11, 13, 15, 17, and 29-31 have been amended, claims 3, 12, 14, 18-28, 32-47 have been cancelled, and claims 48-61 have been newly added.

Applicants respectfully request reconsideration and withdrawal of all outstanding rejections.

Rejection under 35 U.S.C. §112, Second Paragraph

Claims 29-31 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection and reconsideration is requested.

Without conceding the propriety of this rejection, Applicants submit that claims 29-31 have been amended to recite that a test strip is used in the kit for diagnosing a TSE. Support for this amendment may be found, for example, in the specification as originally filed, at least at page 11, paragraph [00044].

In view of the amendments and remarks presented above, Applicants respectfully request withdrawal of the rejection of claims 29-31 under 35 U.S.C. §112, second paragraph.

Rejection under 35 U.S.C. §112, First Paragraph

Claims 1-6, 8-19, 21, 22, 29-38, and 40-46 were rejected under 35 U.S.C. §112, first paragraph. The Office Action continues to take the position that the claims lack enablement for the reasons set forth on pages 2-3. Applicants respectfully traverse this rejection and reconsideration is requested.

Applicants submit that the amendments to the claims set forth above clarify that the comparison being made in order to determine whether or not a subject is suffering from BSE, vCJD, or CJD is made with respect to a reference amount of a polypeptide found in a non-infected subject.

Further, Applicants again submit that it is well understood that for *in vitro* diagnostic assays, the signal in a test sample is compared against a signal from a normal or control reference sample. There is no requirement that the signal of the normal or control reference sample has to have an absolute value. Applicants further submit that one skilled in the art would understand that the size of the signal of the protein peaks are compared with diseased and healthy samples to identify the discriminatory species, and that there are no specific "cut-off values for discriminating between diseased and healthy patients." *See* Office Action, page 3. The differences need only be "significant." *See* paragraph [0055]. Thus, Applicants again submit that no absolute threshold is applied or required in order to carry out the methods or use the test kits of the presently-claimed invention.

In view of the amendments and remarks set forth above, Applicants respectfully request withdrawal of the rejection of claims 1-6, 8-19, 21, 22, 29-38, and 40-46 under 35 U.S.C. §112, first paragraph.

CONCLUSION

Applicants respectfully submit that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in condition for allowance, the Examiner is invited to contact Applicants' undersigned counsel at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

In the event that this paper is not being timely filed, the Applicants respectfully petition for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to Counsel's Deposit Account Number 01-2300, referencing Docket Number 108140-00030.

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Respectfully submitted,

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